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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,586	12/13/2006	Jean Krutmann	7290-105	3304

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EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,586	KRUTMANN, JEAN	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2009 and 20 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 14-19* is/are rejected.

7)☒ Claim(s) *14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 3/20/2009 and 2/9/2009 have been entered.

Claims 11 and 16 have been amended. Claims 1-10 and 12-13 have been cancelled. Thus, claims 11 and 14-19 are pending and currently under consideration.

WITHDRAWN REJECTIONS

2. In view of Applicant's cancellation of claim 12, the objection to claim 12 is herein withdrawn.

3. In view of Applicant's amendment to claim 11, the rejection of claims 11 and 14-19 under 35 U.S.C., first paragraph, for lack of written description, are herein withdrawn.

4. In view of Applicant's amendment to claim 16, the rejection of claim 16 under 35 U.S.C. 112, 2nd paragraph for being indefinite is herein withdrawn.

5. In view of Applicant's amendment to claim 11, the rejection of claims 11, 14, and 17 under 35 U.S.C. 102(b) as anticipated by Sauermann (DE 10133202 A1) is herein withdrawn.

6. In view of Applicant's amendment to claim 11, the rejection of claims 15-16 under 35 U.S.C. 103(a) as obvious over Sauermann (DE 10133202 A1) is herein withdrawn.

7. In view of Applicant's cancellation of claims 12-13, the rejection of claims 12-13 under 35 U.S.C. 103(a) as obvious over Buchholz et al. (US 2004/0053860 A1) is herein withdrawn.

Response to Arguments

Applicant's arguments filed 2/9/2009 have been fully considered but they are not persuasive.

Applicant argues that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristics" of the claimed invention, and thus Buchholz et al. is evidence that flavonoids materially affect the basic and novel characteristics of the invention. In response it is respectfully submitted that it is not clear by the wording in claim 11 if applicant is intending to limit the method steps, the components in the composition or both (see 112, 2nd paragraph rejection *infra*). Furthermore, it is unclear if the flavonoids do materially affect the basic and novel characteristics of the invention,

because claim 17 indicates that antiphlogistics are within the scope of the invention. Buchholz et al. teach that compounds of formula I (i.e. flavonoids) have anti-inflammatory and inflammation inhibiting properties (see page 4, section [0045]). Thus, flavonoids can be considered to be antiphlogistic (anti-inflammatory) compounds and are therefore within the scope of the invention.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

REJECTIONS

The following rejections and/or objections are either reiterated from the 11/21/2008 office action or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application.

Claim Objections

8. Claim 14 is objected to because of the following informalities: the recitation of "comprising" in the phrase "wherein the dermatological composition comprises a tincture, lotion..." does not make sense. The phrase should read "wherein the dermatological composition is a tincture, lotion..." to properly reflect that the composition is one form does not contain multiple forms. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the recitation of "flexible liposomes" is indefinite because flexible is a subjective term, and thus it is unclear to what degree of rigidity the liposomes can possess and still be considered flexible. For examination purposes and in the interest of compact prosecution, all liposomes will be considered to be "flexible" unless otherwise stated.

In claim 11, the recitation of "treating neurodermatitis consisting essentially of a topical application of a dermatological preparation of an osmolyte..." is indefinite because it is unclear Applicant intends to limit the method steps to the topical application, or if the composition itself is limited to components to the osmolytes listed or salts thereof. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

Thus, if Applicants intents to limit the method steps to the topical application of a dermatological composition, the components in the composition are not limited to the osmolyte and components that do not materially affect the basic and novel

characteristics of the invention. If Applicant intends to limit the components in the composition, then the method steps are not limited.

Furthermore if the latter interpretation is intended, claims 17-19 indefinite because they are broader in scope than claim 11. Claim 11 is limited to compositions wherein the active agent is an osmolyte, while claims 17-19 contain additional active agents other than the active agent. Thus, claims 17-19 appear to be broader in scope than claim 11, the claim from which claims 17-19 depend. A dependent claim cannot be broader in scope that the claim(s) from which it depends.

Claims 14-15 are rejected for being dependent on a rejected base claim. For examination purposes, and in the interest of compact prosecution, claim 11 will be interpreted as limited to a composition containing an osmolyte ***and*** any one of the components listed in claims 18-19 (i.e. analgetics, antiphlogistics, fungistats, etc.) since their inclusion seems to indicate these components are within the scope of the invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 11 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchholz et al. (US 2004/0053860 A1).

The instant claims are directed to methods of treating neurodermatitis consisting essentially of topical application of a dermatological preparation of an osmolyte or pharmaceutically acceptable salt thereof to a patient in need thereof, wherein said osmolyte is as ectoine or hydroxyectoine or pharmacologically compatible salt thereof. The preparation (**as best understood**, see 112, 2nd paragraph rejection *supra*) also contains additional active agents selected from analgetics, antiphlogistics, antipruritc substances, antibiotics, fungistats, fungicides, glucocorticoids, or calcineurin inhibitors (instant claims 17-19).

Buchholz et al. teach the use of flavonoid derivatives for the preparation of cosmetic, dermatological, or pharmaceutical suitable for topical application, suitable for the prevention and/or treatment of eczema, particularly atopic eczema (also referred to as endogenous eczema and neurodermatitis) (see abstract; page 1, section [0004]; page 3, section [0026]; page 4, section [0034]). The flavonoids (compounds of formula

I) taught by Buchholz et al. have anti-inflammatory and inflammation-inhibiting properties and thus are considered antiphlogistics as claimed in the instant claim 18 (see page 4, section [0045]). Buchholz further teach that the formulations may further comprise ectoin, and that formulations comprising ectoin and tiliroside (a flavonoid derivative) are particularly advantageous (see page 13, section [0014). Buchholz et al. explicitly teach an example of an O/W cream comprises ectoin and tiliroside, *inter alia* (see page 17, Example 4). Hydroxyectoin is also listed as a possible active ingredient (see page 13, section [0015]-[0016]). Glucocorticoids may optionally be present in the preparation comprising flavonoids for their inflammation inhibiting action (see pages 3-4, sections [0027]-[0031] and [0033]-[0035]). Buchholz et al. also teach the formulations may comprise liposomes, which include active ingredients (see page 14, section [0130]).

Buchholz et al. do not explicitly teach treating neurodermatitis consisting essentially of topical application of a dermatological preparation comprising an osmolyte (i.e. ectoin). Buchholz et al. also do not explicitly teach preparations comprising an osmolyte and an active agent (i.e. glucocorticoid, or flavonoid) for topical application in a method for treating neurodermatitis as claimed in the instant claims 17-19.

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat neurodermatitis by topically applying the composition comprising ectoin (an osmolyte) and tiliroside (an additional active agent and antiphlogistic) taught by Buchholz et al. One of ordinary skill in the art would have been motivated to treat neurodermatitis with a composition comprising ectoin and tiliroside with a reasonable

expectation of success because Buchholz et al. teach the formulation containing tiliroside and ectoin are particularly advantageous, and because it is obvious to use said composition for its intended use in the prevention and/or treatment of atopic eczema (neurodermatitis).

In regards to claim 16, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the tiliroside and ectoin in a liposome as taught by Buchholz et al. One of ordinary skill in the art would have been motivated to put the ectoin in the liposome with a reasonable expectation of success because Buchholz et al. teach the formulations may comprise liposomes, the active ingredients are included in the liposomes, and ectoin is an active ingredient.

In regards to claim 19, it would have been obvious to one of ordinary skill in the art at the time of the invention to add a glucocorticoid as taught by Buchholz et al. to the composition comprising ectoin and tiliroside taught by Buchholz. One of ordinary skill in the art would have been motivated to do to provide the inflammation inhibiting action of the glucocorticoid. One of ordinary skill in the art would have had a reasonable expectation of success in doing so because Buchholz et al. clearly teach that one or more further active ingredients can be added to the composition comprising the flavonoid derivative, and lists glucocorticoids, ectoin, and hydroxyectoin as additional active agents. Glucocorticoids are considered to be within the scope of the invention since they are specifically listed in claim 19. It is also noted that glucocorticoids are considered to be antiphlogistics because of their anti-inflammatory action.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617